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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,358	08/25/2003	Charles Larry Bisgaier	5790-C1	2219

7590 07/12/2006

Heidi M. Berven
Warner-Lambert Company, LLC
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,358	CHARLES LARRY BISGAIER ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/2/2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office action is in reply to applicant's response of 5/2/2006. Claims 1 and 4-5 remain pending in this application, which claims are unamended from the previous examination thereof.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 4-5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Roth (US 5,273,995) in view of Lee et al. (US 5,489,611) Hunninghake et al., Wanner et al. and Medline abstract 96306618 for the reasons of record.

Roth explicitly discloses atorvastatin calcium, i.e. Lipitor as a HMG-CoA reductase inhibitor (column 1; Example 10, columns 14-16; claim 6). Treatment of humans suffering from hypercholesterolemia is taught (column 2, lines 48-53). Use as hypolipidemic or hypocholesterolemic agents is disclosed (column 9, lines 14-15). Combined use with other active therapeutic agents is taught (column 9, lines 28-29).

Roth does not expressly disclose a pharmaceutical composition consisting of Lipitor + retinoid Lp(a) inhibitor + carrier.

Lee et al. disclose Lp(a) lowering retinoids such as those recited in applicant's claims 4-5. See Lee's claims 1-11.

Hunninghake et al. disclose a different statin drug, pravastatin, also with HMG-CoA reductase inhibitor activity, does not significantly affect Lp(a) concentrations (abstract; page 578, table and text below). Wanner et al. similarly disclose a different statin drug, simvastatin, also with HMG-CoA reductase inhibitor activity, does not affect Lp(a) concentrations (abstract; pp. 141-143). Medline abstract 96306618 similarly disclose that the use of a different statin drug, fluvastatin, had no short term effect on Lp(a) levels.

It is without question that the ordinary skilled artisan would have known, before the earliest effective filing date of this application, that elevated levels of Lp(a) represented a risk factor for cardiovascular disease. Further, there was sufficient evidence that numerous statin drugs with HMG CoA reductase inhibitor activity were not effective in reducing Lp(a) levels. Therefore, the ordinary skilled artisan in this field would have been quite motivated to enhance the hypocholesterolemic or hypolipidemic actions of Lipitor with Lee's retinoids to lower Lp(a) levels. The combination of two ingredients would have been advantageous because it would have obtained the hypocholesterolemic and hypolipidemic activity of Lipitor and the added benefit of Lp(a) lowering activity of retinoids. To date, applicant has failed to provide any objective evidence of nonobviousness that may rebut the prima facie case of obviousness established herein. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made,

because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Applicant's arguments filed on 5/2/2006 have been given due consideration but they were deemed unpersuasive. Applicant cites Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Int. 1993) for the authority that a prima facie case of obviousness requires more than individual teachings in the art. The Examiner is well aware of the proper standard to apply for an obviousness ground of rejection. The Board further stated in Levengood, "it is necessary for the examiner to present *evidence*, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention" (emphasis in the original). The Examiner has amply met this requirement. As stated earlier, it is without question that the ordinary skilled artisan would have known, before the earliest effective filing date of this application, that elevated levels of Lp(a) represented a risk factor for cardiovascular disease. Further, there was sufficient evidence that numerous statin drugs with HMG CoA reductase inhibitor activity were not effective in reducing Lp(a) levels. As a result, the ordinary skilled artisan in this field would have been quite motivated to enhance the hypocholesterolemic or hypolipidemic actions of Lipitor with Lee's retinoids to lower Lp(a) levels. The combination of two ingredients would have been advantageous

because it would have obtained the hypocholesterolemic and hypolipidemic activity of Lipitor and the added benefit of Lp(a) lowering activity of retinoids. The ordinary skilled artisan would thus have been led to combine the relevant teachings of the applied references to arrive at the claimed invention.

For these reasons, this ground of rejection must be maintained. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600